Corrected Exhibit C

to

Memorandum of Law

in Support of

Defendant's Motion to

Compel Discovery and

Disclosure of Material

and/or Exculpatory Information

U.S. Department of Justice

Office of Consumer Litigation

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January 26, 2011

Via Email (whassler@steptoe.com)

William T. Hassler, Esq.
Steptoe & Johnson LLP
1330 Connecticut Ave., NW
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Re: *United States v. Lauren Stevens*, RWT-10-0694 (D. Md.)

Dear Mr. Hassler:

Pursuant to Fed. R. Crim. P. 16 and the Protective Order, the government has attached redacted copies of documents bates stamped FDA 196, 197, and 209.

Pursuant to the government's discovery responsibilities and your inquiries, this letter also provides information related to the inquiry into GlaxoSmithKline's promotion of Wellbutrin that was conducted by the Food and Drug Administration's Division of Drug, Marketing, Advertising, and Communications ("the DDMAC inquiry").

On April 8, 2003, the Department of Justice ("the Department") notified the FDA that the Department had opened an investigation into GSK's promotion of various drugs, including Wellbutrin. On May 8, 2003, the Department asked the FDA for copies of all documents generated in connection with the DDMAC inquiry. On June 30, 2003, the FDA provided the Department with its documents and materials related to the DDMAC inquiry. The FDA did not pursue or complete the DDMAC inquiry upon learning of the Department's investigation.

All of the FDA documents of which the Department is aware that fall within the definition of Fed. R. Crim. P. 16(a)(1)(E) have been produced to you. The Department has not produced a small number of FDA email messages from 2002 regarding whether information GSK submitted to the FDA in response to the DDMAC inquiry would be subject to disclosures under the Freedom of Information Act and from 2003 regarding the Department's request for documents related to the DDMAC inquiry. These documents are not material to preparing the defense; the government does not intend to use them in its case-in-chief at trial; and they were not obtained from nor do they belong to the defendant. The documents that are not being produced are protected by Rule 16(a)(2), the attorney-client privilege, and/or the deliberative process privilege. The government is unaware of any legal authority that would require us to provide you with a privilege log of documents not being produced that are outside Rule 16's scope.

The government is also not producing post-2003 internal FDA email messages that are similarly privileged and outside the scope of Rule 16. However, even though 18 U.S.C. § 3500 does not require the government to provide prospective government witness' statements until the time of trial, set forth below are statements made by FDA employees about this matter, which are embedded in emails that are privileged.

On November 9, 2006, Sonny Saini stated:

I have not worked in DDMAC since Dec. 2004 and have limited recollection of the issue with GSK. I do recall that we did send DOJ per their request documents regarding GSK's promotion of Wellbutrin. I believe the issue had to do with "off-label" promotion of Wellbutrin. I am sure there should be documents in the document room regarding this. There were teleconferences with GSK and DDMAC regarding the submissions that were requested by DDMAC. This is all I recall off the top of my head.

On November 9, 2006, Lisa Stockbridge stated:

I barely remember working on wellbutrin ads. I haven't been in DDMAC since March 2004 and I don't have any historical background files. So, I am not sure how I can help you. All I remember about Wellbutrin ads is a problem with Quality of Life claims. That would have involved a review by Elain Hu (? She is married now and I don't know her new last name.) It also involved DTC pieces, so Joan Hankin may be someone to talk to. Hope this helps, Lisa

On November 15, 2006, Lesley Frank stated:

"After further review the play stands as called on the field" I don't think we will be of much help here. I seem to recall Sonny showing me a few of the "marked" slides in his office and that he was not terribly excited (they were off-label). I do recall GSK trying to fit themselves under the ISSEA guidance as well as a perceived unsolicited policy. There was some mea culpa that they "promptly" corrected. Not enough to go after I would guess (that and the First Amendment issues). I just wish there was official closure with a closeout letter. (Would tie it up nicely, that's all. An affirmative statement by us stating that "we relied on GSK's representations and that's why we consider the matter closed" would have been nice – especially if those representations were false.) - L

On March 26, 2009, Lisa Stockbridge stated:

Wow! I really don't remember participating in those teleconferences. However, I do remember discussions about the whole burden of a rolling submission that Lesley negotiated with GSK. I don't know if you were present during her

questioning. Basically, when things got to Lesley's level (DDMAC's internal counsel), everyone else took a back seat. You can sense this from the memos.

On April 15, 2009, Lisa Stockbridge stated:

There is nothing much to say. I still don't know anything about this. All I know is that Sonny Saini and Lesley Frank did this. I was just the mentor for Sonny, and it was late in his training so I was less involved.

Please let us know if you have any questions concerning these matters.

Sincerely,

Patrick Jasperse

Patrick Jasperse
Trial Attorney

Enclosures

cc: Sara Bloom, Assistant U.S. Attorney
Steven Tave, Associate Chief Counsel, FDA

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

UNITED STATES OF AMERICA	**FILED UNDER SEAL**
v.	**No. 10-cr-694-RWT**
LAUREN STEVENS,	
Defendant.	

CERTIFICATE OF SERVICE

I hereby certify that on March 3, 2011, a true and correct copy of Defendant's Motion to Seal and Defendant's Corrected Exhibit to Memorandum of Law in Support of Defendant's Motion to Compel Discovery and Disclosure of Material and/or Exculpatory Information was served via electronic mail upon the following individuals:

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